

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gregory J. LaRosa, Christopher Horvath, Walter Newman, S. Tarran Jones,
Siobhan H. O'Brien and Theresa O'Keefe

Divisional Application of:

Application No.: 09/497,625

Filed: February 3, 2000

For: HUMANIZED ANTI-CCR2 ANTIBODIES AND METHODS OF USE THEREFOR

Date: <u>27 January 2004</u> EXPRESS MAIL LABEL NO. <u>EV214944796 US</u>
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☐ Copies of the cited references are enclosed.
 - ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☒ Copies of the cited references AB2, AN2-AP2, and AX7-AR8 are enclosed. References AA-AA2, AL-AM2 and AR-AW7 were entered in prior application, U.S. Application No. 09/497,625, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of these cited references (AA-AA2, AL-AM2 and AR-AW7).
 - ☒ Some of the listed references were cited in the enclosed International Search Reports in counterpart foreign applications.
 - ☒ The "concise explanation" requirement (non-English references) for reference AL under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☒ the English language abstract on the front page of the published PCT application which is reference AL.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated: 1/27/04

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION December 16, 2003 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1855.1052-028		APPLICATION NO.	
	FIRST NAMED INVENTOR Gregory J. LaRosa		FILING DATE	
	EXAMINER	CONFIRMATION NO.	GROUP	

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	6,084,075	07-04-2000	Lind, <i>et al.</i>
	AB	5,543,503	08-06-1996	Chuntharapai, <i>et al.</i>
	AC	5,440,021	08-08-1995	Chuntharapai, <i>et al.</i>
	AD	5,859,205	01-12-1999	Adair, <i>et al.</i>
	AE	5,693,762	12-02-1997	Queen, <i>et al.</i>
	AF	5,693,761	12-02-1997	Queen, <i>et al.</i>
	AG	5,585,089	12-17-1996	Queen, <i>et al.</i>
	AH	5,225,539	07-06-1993	Winter
	AI	4,816,397	03-28-1989	Boss, <i>et al.</i>
	AJ	4,816,567	03-28-1989	Cabilly, <i>et al.</i>
	AK	5,707,815	01-13-1998	Charo, <i>et al.</i>
	AA2	5,571,713	11-05-1996	Lyle, <i>et al.</i>
	AB2	5,985,279 ✓	11-16-1999	Waldmann, <i>et al.</i>
	AC2			
	AD2			
	AE2			
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FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	PCT WO 95/08576	03-30-1995	LIPP, Martin		X
	AM	PCT WO 99/15666	04-01-1999	ICOS Corporation		
	AN	PCT WO 97/31949	09-04-1997	Pharmacia & UpJohn AB and Conseio Superior De Investigaciones		
	AO	PCT WO 95/19436	07-20-1995	The Regents of the University of California		
	AP	PCT WO 98/44953	10-15-1998	Max-Planck-Gesellschaft Zur Förderung Der Wissenschaften E.V.		
	AQ	PCT WO 94/09128	04-28-1994	Mallinckrodt Medical, Inc.		
	AL2	PCT WO 91/09967	07-11-1991	Celltech Limited		
	AM2	PCT WO 00/05265	02-03-2000	LeukoSite, Inc.		
	AN2	PCT WO 97/47319 ✓	12-18-1997	Progenics Pharmaceuticals, Inc., and Aaron Diamond Aids Research Centre		
	AO2	PCT WO 94/12214 ✓	06-09-1994	Protein Design Labs, Inc.		
	AP2	PCT WO 98/42360 ✓	10-01-1998	Massachusetts Institute of Technology		
	AQ2					
	AL3					
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR		Förster, R. <i>et al.</i> , "A general method for screening mAbs specific for G-protein coupled receptors as exemplified by using epitope tagged BLR1-transfected 293 cells and solid-phase cell ELISA", <i>Biochemical and Biophysical Research Communications</i> 196(3):1496-1503 (1993).
AS		Boring, L. <i>et al.</i> , "Decreased lesion formation in CCR2 ^{-/-} mice reveals a role for chemokines in the initiation of atherosclerosis," <i>Nature</i> 394(27):894-897 (1998).
AT		Ylä-Herttuala, S. <i>et al.</i> , "Expression of monocyte chemoattractant protein 1 in macrophage-rich areas of human and rabbit atherosclerotic lesions," <i>Proc. Natl. Acad. Sci., USA</i> 88:5252-5256 (1991).
AU		Taubman, M.B. <i>et al.</i> , "JE mRNA Accumulates Rapidly in Aortic Injury and in Platelet-Derived Growth Factor-Stimulated Vascular Smooth Muscle Cells," <i>Circulation Research</i> 70(2):314-325 (1992).
AV		Feng, A. <i>et al.</i> , "Red Wine Inhibits Monocyte Chemotactic Protein-1 Expression and Modestly Reduces Neointimal Hyperplasia After Balloon Injury in Cholesterol-Fed Rabbits," <i>Circulation</i> 100:2254-2259 (1999).
AW		Lukacs, N.W. <i>et al.</i> , "Production of Monocyte Chemoattractant Protein-1 and Macrophage Inflammatory Protein-1 α by Inflammatory Granuloma Fibroblasts," <i>American Journal of Pathology</i> 144(4):711-718 (1994).
AX		Koch, A.E., <i>et al.</i> , "Enhanced Production of Monocyte Chemoattractant Protein-1 in Rheumatoid Arthritis," <i>The Jour. of Clin. Invest.</i> 90:772-779 (1992).
AY		Harigai, M. <i>et al.</i> , "Monocyte Chemoattractant Protein-1 (MCP-1) in Inflammatory Joint Diseases and Its Involvement in the Cytokine Network of Rheumatoid Synovium," <i>Clin. Immun. and Immunopathology</i> 69(1):83-91 (1993).
AZ		Villiger, P.M. <i>et al.</i> , "Production of Monocyte Chemoattractant Protein-1 by Inflamed Synovial Tissue and Cultured Synoviocytes," <i>J. Immunol.</i> 149(2):722-727 (1992).
AR2		Reinecker, H.C. <i>et al.</i> , "Monocyte-Chemoattractant Protein 1 Gene Expression in Intestinal Epithelial Cells and Inflammatory Bowel Disease Mucosa," <i>Gastroenterology</i> 108(1):40-50 (1995).
AS2		Nelken, N.A. <i>et al.</i> , "Monocyte Chemoattractant Protein-1 in Human Atheromatous Plaques," <i>J. Clin. Invest.</i> 88:1121-1127 (1991).

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AT2	Grewal, I.S. <i>et al.</i> , "Transgenic Monocyte Chemoattractant Protein-1 (MCP-1) in Pancreatic Islets Produces Monocyte-Rich Insulitis Without Diabetes," <i>J. Immunol.</i> 159:401-408 (1997).	
AU2	Yu, X. <i>et al.</i> , "Elevated expression of monocyte chemoattractant protein 1 by vascular smooth muscle cells in hypercholesterolemic primates," <i>Proc. Natl. Acad. Sci., USA</i> 89:6953-6957 (1992).	
AV2	Berman, J.W. <i>et al.</i> , "Localization of Monocyte Chemoattractant Peptide-1 Expression in the Central Nervous System in Experimental Autoimmune Encephalomyelitis and Trauma in the Rat," <i>J. Immunol.</i> 156:3017-3023 (1996).	
AW2	Lukacs, N.W. <i>et al.</i> , "The Production of Chemotactic Cytokines an Allogeneic Response," <i>Amer. Jour. of Pathology</i> 143(4):1179-1188 (1993).	
AX2	Christensen, P.J. <i>et al.</i> , "Characterization of the Production of Monocyte Chemoattractant Protein-1 and IL-8 in an Allogeneic Immune Response," <i>The Journal of Immunology</i> 151(3):1205-1213 (1993).	
AY2	Rand, M.L. <i>et al.</i> , "Inhibition of T Cell Recruitment and Cutaneous Delayed-Type Hypersensitivity-Induced Inflammation with Antibodies to Monocyte Chemoattractant Protein-1," <i>Amer. Jour. of Pathology</i> , 148(3):855-864 (1996).	
AZ2	Jones, M.L. and Warren, J.S., "Monocyte Chemoattractant Protein 1 in a Rat Model of Pulmonary Granulomatosis," <i>Laboratory Investigation</i> 66(4):498-503 (1992).	
AR3	Lloyd, C.M. <i>et al.</i> , "Role of MCP-1 and RANTES in inflammation and progression to fibrosis during murine crescentic nephritis," <i>Journal of Leukocyte Biology</i> 62:676-680 (1997).	
AS3	Flory, C.M. <i>et al.</i> , "Pulmonary Granuloma Formation in the Rat is Partially Dependent on Monocyte Chemoattractant Protein 1," <i>Laboratory Invest.</i> , 69(4):396-404 (1993).	
AT3	Jones, M.L. <i>et al.</i> , "Potential Role of Monocyte Chemoattractant Protein 1/JE In Monocyte/Macrophage-Dependent IgA Immune Complex Alveolitis in the Rat," <i>J. Immunol.</i> 149(6):2147-2154 (1992).	
AU3	Gu, L. <i>et al.</i> , "Absence of Monocyte Chemoattractant Protein-1 Reduces Atherosclerosis in Low Density Lipoprotein Receptor-Deficient Mice," <i>Molecular Cell</i> , 2(2):275-281 (1998).	
AV3	Tesch, G.H., <i>et al.</i> , "Monocyte chemoattractant protein-1 promotes macrophage-mediated tubular injury, but not glomerular injury, in nephrotoxic serum nephritis," <i>J. Clin. Invest.</i> 103(1):73-80 (1999).	

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	AW3	Lu, B., <i>et al.</i> , "Abnormalities in Monocyte Recruitment and Cytokine Expression in Monocyte Chemoattractant Protein 1-deficient Mice," <i>J. Exp. Med.</i> 187(4):601-608 (1998).
	AX3	Rutledge, B.J. <i>et al.</i> , "High Level Monocyte Chemoattractant Protein-1 Expression in Transgenic Mice Increases Their Susceptibility to Intracellular Pathogens," <i>J. Immunol.</i> 155:4838-4843 (1995).
	AY3	Gunn, M.D. <i>et al.</i> , "Monocyte Chemoattractant Protein-1 Is Sufficient for the Chemotaxis of Monocytes and Lymphocytes in Transgenic Mice but Requires an Additional Stimulus for Inflammatory Activation," <i>J. Immunol.</i> 158:376-383 (1997).
	AZ3	Chensue, S.W. <i>et al.</i> , "Role of Monocyte Chemoattractant Protein-1 (MCP-1) in Th1 (Mycobacterial) and Th2 (Schistosomal) Antigen-Induced Granuloma Formation," <i>J. Immunol.</i> 157:4602-4608 (1996).
	AR4	Lukacs, N.W. <i>et al.</i> , "Differential Recruitment of Leukocyte Populations and Alteration of Airway Hyperreactivity by C-C Family Chemokines in Allergic Airway Inflammation," <i>J. Immunol.</i> 158:4398-4404 (1997).
	AS4	Tang, W.W. <i>et al.</i> , "Chemokine Expression in Experimental Tubulointerstitial Nephritis," <i>J. Immunol.</i> 159:870-876 (1997).
	AT4	Fujinaka, H. <i>et al.</i> , "Suppression of Anti-Glomerular Basement Membrane Nephritis by Administration of Anti-Monocyte Chemoattractant Protein-1 Antibody in WKY Rats," <i>Jour. of the Amer. Soc. of Nephrology</i> 8:1174-1178 (1997).
	AU4	Lloyd, C.M., <i>et al.</i> , "RANTES and Monocyte Chemoattractant Protein-1 (MCP-1) Play an Important Role in the Inflammatory Phase of Crescentic Nephritis, but Only MCP-1 Is Involved in Crescent Formation and Interstitial Fibrosis," <i>J. of Exp. Med.</i> 185(7):1371-1380 (1997).
	AV4	Furukawa, Y. <i>et al.</i> , "Anti-Monocyte Chemoattractant Protein-1/Monocyte Chemotactic and Activating Factor Antibody Inhibits Neointimal Hyperplasia in Injured Rat Carotid Arteries," <i>Circulation Research</i> 84:306-314 (1999).
	AW4	Zisman, D.A. <i>et al.</i> , "MCP-1 Protects Mice in Lethal Endotoxemia," <i>J. Clin. Invest.</i> 99(12):2832-2836 (1997).
	AX4	Schimmer, R.C., <i>et al.</i> , "Streptococcal Cell Wall-Induced Arthritis: Requirements for IL-4, IL-10, IFN- γ , and Monocyte Chemoattractant Protein-1," <i>J. Immunol.</i> 160:1466-1471 (1998).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AY4	Ogata, H. <i>et al.</i> , "The Role of Monocyte Chemoattractant Protein-1 (MCP-1) in the Pathogenesis of Collagen-Induced Arthritis in Rats," <i>J. Pathol.</i> 182:106-114 (1997).	
AZ4	Huffnagle, G.B. <i>et al.</i> , "The Role of Monocyte Chemotactic Protein-1 (MCP-1) in the Recruitment of Monocytes and CD4 ⁺ T Cells During a Pulmonary <i>Cryptococcus Neoformans</i> Infection," <i>J. Immunol.</i> 155:4790-4797 (1995).	
AR5	Gong, J. <i>et al.</i> , "An Antagonist of Monocyte Chemoattractant Protein 1 (MCP-1) Inhibits Arthritis in the MRL- <i>lpr</i> Mouse Model," <i>J. Exp. Med.</i> 186(1):131-137 (1997).	
AS5	Boring, L. <i>et al.</i> , "Impaired Monocyte Migration and Reduced Type 1 (Th1) Cytokine Responses in C-C Chemokine Receptor 2 Knockout Mice," <i>J. Clin. Invest.</i> 100(10):2552-2561 (1997).	
AT5	Kuziel, W.A. <i>et al.</i> , "Severe reduction in leukocyte adhesion and monocyte extravasation in mice deficient in CC chemokine receptor 2," <i>Proc. Natl. Acad. of Sci., USA</i> 94(22):12053-12058 (1997).	
AU5	Kurihara, T. <i>et al.</i> , "Defects in Macrophage Recruitment and Host Defense in Mice Lacking the CCR2 Chemokine Receptor," <i>J. Exp. Med.</i> 186(10):1757-1762 (1997).	
AV5	Jiang, Y. <i>et al.</i> , "Chemokine receptor expression in cultured glia and rat experimental allergic encephalomyelitis," <i>J. Neuroimmunology</i> 86:1-12(1998).	
AW5	Chuntharapai <i>et al.</i> , "Generation of Monoclonal Antibodies to Chemokine Receptors", <i>Methods in Enzymology</i> 288: 15-27 (1997).	
AX5	Montecclaro, Felipe S. and Charo, Israel F., "The Amino-Terminal Domain of CCR2 Is Both Necessary and Sufficient for High Affinity Binding of Monocyte Chemoattractant Protein 1", <i>The Journal of Biological Chemistry</i> 272(37):23186-23190 (1997).	
AY5	Qin, Shixin <i>et al.</i> , "Expression of Monocyte Chemoattractant Protein-1 and Interleukin-8 Receptors on Subsets of T Cells: Correlation with Transendothelial Chemotactic Potential," <i>Eur. J. Immunol.</i> 26:640-647 (1996).	
AZ5	Yamagami, Shinsuke <i>et al.</i> , "cDNA Cloning and Functional Expression of a Human Monocyte Chemoattractant Protein 1 Receptor," <i>Biochemical and Biophysical Research Communications</i> 202(2):1156-1162 (1994).	

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AR6	Charo, Israel, F. <i>et al.</i> , "Molecular Cloning and Functional Expression of Two Monocyte Chemoattractant Protein 1 Receptors Reveals Alternative Splicing of the Carboxyl-Terminal Tails," <i>Proc. Natl. Acad. Sci., USA.</i> 91:2752-2756 (1994).
AS6	Aragay, A.M. <i>et al.</i> , "Monocyte Chemoattractant Protein-1-Induced CCR2B Receptor Desensitization Mediated by the G Protein-Coupled Receptor Kinase 2," <i>Proc. Natl. Acad. Sci. USA</i> , 95:2985-2990 (1998).
AT6	Frade, Jose M.R. <i>et al.</i> , "Characterization of the CCR2 Chemokine Receptor: Functional CCR2 Receptor Expression in B Cells," <i>J. Immunol.</i> 159(11):5576-5584 (1997).
AU6	Frade, Jose M.R. <i>et al.</i> , "The Amino-Terminal Domain of the CCR2 Chemokine Receptor Acts as Coreceptor for HIV-1 Infection," <i>J. Clin. Invest.</i> 100(3):497-502 (1997).
AV6	Wong, Lu-Min <i>et al.</i> , "Organization and Differential Expression of the Human Monocyte Chemoattractant Protein 1 Receptor Gene," <i>The Journal of Biological Chemistry</i> 272(2):1038-1045 (1997).
AW6	Kurihara, Takao and Bravo, Rodrigo, "Cloning and Functional Expression of mCCR2, a Murine Receptor for the C-C Chemokines JE and FIC," <i>The Journal of Biological Chemistry</i> 271(20):11603-11606 (1996).
AX6	Grimm, M.C. <i>et al.</i> , "Enhanced expression and production of monocyte chemoattractant protein-1 in inflammatory bowel disease mucosa," <i>Journal of Leukocyte Biology</i> 59:804-812 (1996).
AY6	Izikson, L. <i>et al.</i> , "Resistance to Experimental Autoimmune Encephalomyelitis in Mice Lacking the CC Chemokine Receptor (CCR)2," <i>J. Exp. Med.</i> 192(7):1075-1080 (2000).
AZ6	Fife, B.T. <i>et al.</i> , "CC Chemokine Receptor 2 Is Critical for Induction of Experimental Autoimmune Encephalomyelitis," <i>J. Exp. Med.</i> 192(6):899-905 (2000).
AR7	Sanz, I., <i>et al.</i> , "Evidence That Autoantibodies Can Be Unmutated Copies of Germline Genes," <i>The Journal of Immunology</i> 142(3):883-887 (1989).
AS7	Chastagner, P., <i>et al.</i> , "Cloning of a gene encoding a lupus-associated human autoantibody V _k region using the polymerase chain reaction and degenerate primers," <i>Gene</i> 101:305-306 (1991).
AT7	Chothia, C., <i>et al.</i> , "Conformations of immunoglobulin hypervariable regions," <i>Nature</i> 342:877-883 (1989).

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	AU7	Welt, <i>et al.</i> , "Targeting CCR-2 or CD18 Inhibits Experimental in-Stent Restenosis in Primates. Inhibitory Potential Depends on Type of Injury and Leukocytes Targeted", <i>Circulation-Journal of the American Heart Association</i> (Abstracts from Scientific Sessions 2000), 102(18): II-247, Abstract 1206 (2000).
	AV7	Huston, James S., <i>et al.</i> , "Engineered antibodies take center stage", <i>Human Antibodies</i> , 10:127-142 (2001).
	AW7	Reichert, Janice M., "Monoclonal antibodies in the clinic", <i>Nature Biotechnology</i> , 19: 819-822 (2001).
✓	AX7	Rudikoff, S., <i>et al.</i> , "Single amino acid substitution altering anitgen-binding specificity," <i>Proc. Natl. Acad. Sci USA</i> , 79: 1979-1983 (1982).
✓	AY7	Paul, William E. , "Fundamental Immunology," <i>Raven Press NY</i> , Chapter 8, page 242 (1993).
	AZ7	Berzofsky, J.A., <i>et al.</i> , "Immunogenicity and Antigen Structure," <i>Fundamental Immunology</i> , 8: 242 (1993).
	AR8	Johnston, B., <i>et al.</i> , "Chronic inflammation upregulates chemokine receptors and induces neutrophil migration to monocyte chemoattractant protein-1," <i>J. Clin. Invest.</i> , 103(9): 1269-1276 (1999).

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